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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,264	02/27/2002	Spiros Fotinos	1581/130	2006
2101	7590	02/26/2004	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			KIM, JENNIFER M	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/084,264

Applicant(s)

FOTINOS, SPIROS

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 23, 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's election with traverse of Group I, claims 1-13, drawn to a patch comprising a breathable layer, a barrier layer, and a volatile agent, classified in class 424, subclass 449 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the claims 1-13 should be grouped along with claims 19, 21/19 and 22/19 because these claims depend from claim 1 and should be included within the examination of claims 1-13. This is not persuasive because the claims are drawn to distinct and separate inventions since the volatile substance can be applied to the subject without the application to the subject and without the adhesive. However, if the elected claims directed to an allowable product, claims directed using the patentable product, presently being withdrawn from consideration as a result of the restriction requirement can be subject to rejoin. It is reminded that those claims do not depend from or otherwise include all the limitations of the allowable product, will NOT be rejoined.

Accordingly, claims 14-22 are withdrawn from consideration since they are non-elected invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 6-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischel-Ghodsian (U.S. Patent No. 5,070,704) of record.

Fischel-Ghodsian teaches controlled device comprising an adhesive layer for adhering to skin or a surface comprising 1) reservoir layer which incorporates an active compound such as air freshner, various fragrances, air fresheners, insecticides, vapor emitting compounds, naturally occurring essential oils, perfumes, 2) a diffusion rate limiting membrane layer, 3) an impermeable backing layer (adjacent to the reservoir layer) that provides a barrier to the diffusion of the active compound and a peeling layer. (abstract, column 3, lines 15-32, column 2, lines 55-67, column 3, lines 15-52, column 4, lines 22-35, lines 64-column 5, line 58, column 6, lines 10-16, claims 1-3).

Fischel-Ghodsian teaches that the reservoir layer of the laminate is in the form of a gelled mixture (an oil and polymer) and a liquid when the active compound is an oil soluble compound. (column 4, lines 64-68). Fischel-Ghodsian teaches that above composition can deliver vapors or liquids for a period of from 1 to 72 hours. (column 2, lines 63-66). It is noted that it is well recognized in the patent law that for composition claim is that portion stated after the term "comprising" therefore applicant's composition claims for a patch read upon the device of above reference. Further, Applicant's recitation in claims 11-13 of an effect does not represent a patentable limitation since such fails to impart any physical limitation to the composition and it is inherent effect of the prior composition since it is drawn to the same active agent (i.e. a volatile active agent).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischel-Ghodsian (U.S. Patent No. 5,070,704) of record.

Fischel-Ghodsian applied as before.

Fischel-Ghodsian teaches the polymer-perfume gel was spread onto the impermeable membrane layer forming the reservoir layer of the laminate and the diffusion rate membrane is then placed adjacent to the reservoir layer. (column 9, lines 40-45).

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Fischel-Ghodsian does not expressly teach the process of making solid layer having been made in order by applying liquid mixture onto the breathable layer of the device and the sealed pouch of the patch.

It would have been obvious to one of ordinary skill in the art to provide sealed pouch enclosing the device taught by Fischel-Ghodsian since it is routine manufacturing process for dispensing a patch or device to store or deliver the product as sterile as possible with its original manufactured condition in order to avoid unwanted contamination by any means. Further, the process of making solid layer of the device by applying a liquid mixture on to the breathable layer is obvious because Fischel-Ghodsian teaches that the gel was spread on to form the reservoir and that diffusion rate limiting membrane was then placed adjacent of the reservoir layer. One of ordinary skill in the art would have been motivated modify the process of Fischel-Ghodsian in any order for the convenience and individual manufacturing preference since the diffusion membrane layer and the reservoir layer is ultimately placed adjacent to each other.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischel-Ghodsian (U.S. Patent No. 5,070,704) as applied to claims 1-3, 6-13, 23 and 24 above, and further in view of Fujita et al. (U.S. Patent No. 5,928,661) and Sweeney (GB 2260494A), all of record.

Fischel-Ghodsian applied as before.

Fischel-Ghodsian teaches that in addition to gelling agents, reservoir may include other materials such as stabilizers. (column 5, lines 20-21).

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Fischel-Ghodsian does not teach the specific wax of ozokerites and sodium stearate in the solid layer.

Fujita et al. teaches controlled release composition comprising volatile plasticizer such as ozokerite. (column 1, line 65-column 2, line 11, column 3, lines 20-28, column 3, line 51- column 4, line 5, particularly, column 4, line 2). Fujita et al. teach that the plasticizer facilitates mixing and kneading the composition. (column 3, line 51- column 4, line 5).

Sweeney teaches fragrant controlled release composition for use as an air freshener comprising a volatile fragrant compound and a binding agent such as sodium stearate. (abstract, page 2, lines 4-7,, page 3, lines 8-12, page 4, lines 7-10, page 8, line 14).

It would have been obvious to one of ordinary skill in the art to incorporate ozokerites and sodium stearate in the reservoir layer (solid layer) of Fischel-Ghodsian composition because Fischel-Ghodsian teaches that the reservoir layer may include other materials and because ozokerite facilitates mixing and kneading of the composition. Further sodium stearate is routinely used in the air freshener composition in controlled release form of volatile fragrant composition as a binding agent. One of ordinary skill in the art would have been motivated to incorporate ozokerite and sodium stearate into Fischel-Ghodsian's reservoir layer and make such modification because they are drawn to same technical fields (constituted with controlled release air freshener related device and well known additives (e.g. plasticizer, binders), and pertinent to the problem which applicant concerned about. MPEP 2141.01(a).

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For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Sreenivasan Padmanabhan  
Supervisory Examiner  
Art Unit 1617

10/20/03

jmk  
October 15, 2003